

Notice of Allowability

Application No.

09/938,956

Applicant(s)

DICOSIMO ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to the amendment to the claimed filed January 7, 2004.

☒ The allowed claim(s) is/are 1,2,7,9,11,13 and 15.

☐ The drawings filed on _____ are accepted by the Examiner.

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

☐ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 12/01 & 3/02

☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____.



Nashaat T. Nashed, Ph. D.
Primary Examiner
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This application contains claims directed to the following patentably distinct species of the claimed invention: (a) multiple species of monoterpene and their genes: limonene, pinene, bornyl diphosphate, β -phellandrene, 1,8-cineole, and sabinene; and (b) host cells: *Methylomonas*, *Methylobacter*, *Methylococcus*, *Methylosinus*, *Methylocystis*, *Methylomicrobium*, *Methanomonas*, *Methylophilus*, *Methylobacillus*, *Methylobacterium*, *Hyphomicrobium*, *Xanthobacter*, *Bacillus*, *Paracoccus*, *Nocardia*, *Arthrobacter*, *Rhodopseudomonas*, *Pseudomonas*, *Candida*, *Hansenula*, *Pichia*, *Torulopsis*, and *Rhodotorula*.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with S. Neil Feltham on January 6, 2004 a provisional election was made without traverse to prosecute the invention as pertain to (a) limonene, and (b) *Methylomonas*.

Also, in response to the election requirement, Applicant filed an amendment on January 6, 2004 and January 7, 2004 affirming their election of species and amended the claims. After entry of the amendments claims 1-4, 7, 9, 11-15, 22 and 23 are pending.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

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by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with S. Neil Feltham on May 25, 2004.

The application has been amended as follows:

Claim 1 (Currently Amended). A method for the production of a monoterpene comprising:

- a) providing a transformed Methylobionas [C1-metabolizing host] cell comprising:
 - (i) [suitable levels of] geranyl pyrophosphate; and
 - (ii) at least one isolated nucleic acid molecule encoding a cyclic terpene synthase selected from the group consisting of limonene synthase, pinene synthase, bornyl synthase, phellandrene synthase, cineole synthase and sabinene synthase under the control of suitable regulatory sequences;
- (b) contacting the Methylobionas [host] cell of step (a) under suitable growth conditions with an effective amount of a C1 carbon substrate whereby a monoterpene compound is produced.

Claim 2 (Currently Amended). A method according to Claim 1 wherein the C1 carbon substrate is [selected from the group consisting of] methane [, methanol, formaldehyde, formic acid, methylated amines, methylated thiols and carbon dioxide].

Claims 3-6 (Canceled).

Claim 7 (Currently Amended). A method according to Claim 1 [4] wherein the [methanotroph] Methylobionas is a high growth methanotrophic strain which comprises a functional Embden-Meyerof carbon pathway, said pathway comprising a gene encoding a pyrophosphate dependent phosphofructokinase enzyme.

Claim 8 (Canceled).

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Claim 9 (Original). A method according to Claim 7 wherein the high growth methanotrophic bacterial strain optionally contains a functional Entner-Doudoroff carbon pathway.

Claim 10 (Canceled)

Claim 11 (Previously Amended). A method according to Claim 7 wherein the high growth methanotrophic bacterial strain is *Methylobacter* 16a having the ATCC designation ATCC PTA 2402.

Claim 12 (Canceled).

Claim 13 (Original). A method according to Claim 1 wherein the monoterpene is selected from the group consisting of limonene, pinene, bornyl diphosphate, β -phellandrene, 1,8-cineole, and sabinene.

Claim 14 (Canceled)

Claim 15 (Currently Amended). A method according to Claim 1 [14] wherein the limonene synthase has the amino sequence as set forth in SEQ ID NO: 6.

Claims 16-23 (Canceled).

Claims 1, 2, 7, 9, 11, 13, and 15 are allowed.

The following is an examiner's statement of reasons for allowance: The application discloses a recombinant method for the synthesis of monoterpenes using *Methylobacter* 16a, which utilizes methane as the sole carbon source for growth. The specification teaches a method of identifying the methanotroph organism, the construction of vectors comprising the nucleic acid encoding a terpene synthase, and transforming the *Methylobacter* 16a with said vector, and culturing the transformed host cell to produce the monoterpene. Since claimed method is not taught or suggested in the prior art, the claims are allowed.

The drawings are objected to because figure 3 contains the chemical names (+)-4S-limonene and names (-)-4S-limonene. That makes the Figure confusing because the absolute configuration should change with the change in the sign of light rotation. In

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another words, one of them should have R configuration whereas the other should have S configuration. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
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